

REMARKS

Reconsideration and reexamination of the subject application are respectfully requested in light of the foregoing amendments and following remarks. The amendments are made without prejudice or disclaimer of Applicants' right to claim any subject matter disclosed in the specification in a subsequently filed continuing application.

1. Status of the Claims

Claims 1-10 are pending. Claims 1-10 stand rejected. Claim 11 is added by the present amendment.

2. Support for the Amendments

The amendments to claim 1 include substitution of the term "an" with the term "the," which is added to clarify the nature of the invention. "SEQ. ID. No." is replaced with "SEQ ID NO" to comport with U.S. practice. The amendments further clarify that the protein and polynucleotide of claims 1 and 2, respectively, are "isolated." Support for an isolated protein and polynucleotide is found throughout the specification, e.g., page 11, line 3, through page 13, line 16.

Claim 1 is further amended to replace a gene of SEQ ID NO: 2 with a polynucleotide that encodes the protein of SEQ ID NO: 1. Support for the amendment is found, for example, at page 4, lines 9-10; page 7, line 6 (encoding gene); and page 10, line 1, *et seq.* (encoding RNA). The Office is further respectfully directed to the Federal Circuit's holding in *In re Wallach*, 378 F.3d 1330, 71 U.S.P.Q.2d 1939 (Fed. Cir. 2004). The Court held that the state of the art has developed such that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it, and that one of ordinary skill in the art would be in possession of the entire genus of DNA sequences that can encode even a partially disclosed protein sequence, even if the individual species within that genus might not have been described. *Wallach*, 71 U.S.P.Q.2d at 1942 (citing with approval M.P.E.P. § 2163(II)(A)(3)(a)(ii), 8th ed., revised February 2001). For this reason, the description of the protein of SEQ ID NO: 1 puts the

artisan in possession of a genus of nucleic acids encoding the protein of SEQ ID NO: 1, which includes the nucleic acid of SEQ ID NO: 2. *See Wallach*, 71 U.S.P.Q.2d at 1942.

The amendments to the specification and Sequence Listing are made to bring the application in compliance with the Sequence Rules, 37 C.F.R. §§ 1.821-825.

3. Notice of Prosecution in a Co-Pending Application

Applicants bring to the Office's attention prosecution in co-pending Application Serial No 10/588,052 ("the '052 application"), titled "Protein with Activity of Hydrolyzing Amylopectin, Starch, Glycogen and Amylose, Gene Encoding the Same, Cell Expressing the Same, and Production Method Thereof." A non-final Office Action was mailed in the '052 application on November 20, 2007. The Office Action cited U.S. Patent No. 6,485,953 ("Kim") and Steyn *et al.*, *Gene* 166: 65-71 (1995) in rejections under 35 U.S.C. § 102(b). The Office Action also cited Kim in view of Standing, *Curr. Opinion Struct. Biol.* 13(5): 595-601 (2003); Sambrook *et al.* **IN MOLECULAR CLONING: A LABORATORY MANUAL**, 2nd ed., Cold Spring Harbor, N.Y., pp 8.46-8.52 and 11.2-11.19 (1989); and U.S. Patent No. 5,643,758 in rejections under 35 U.S.C. § 103.

4. Acceptance of Drawings

Applicants note with appreciation the indication that all the drawings filed on July 31, 2006, are accepted.

5. Acknowledgement of Certified Priority Documents

Applicants note with appreciation the indication that all of the certified priority documents have been received in this matter.

6. Acknowledgement of Information Disclosure Statement

Applicants note with appreciation the acknowledgement of the Information Disclosure Statements filed July 31, 2006, February 16, 2007, and September 10, 2007.¹

¹ The Office Action Summary and the Detailed Action at item 2 refer to various other IDS submission dates,

7. Objection to the Specification

The specification is objected to as not complying with the Sequence Rules, 37 C.F.R. §§ 1.821-825. Specifically, the Office requires that sequences in the specification lack sequence identifiers. The present amendment to the specification adds the required sequence identifiers, along with a substitute paper copy of the Sequence Listing and a CRF. The substitute copy of the Sequence Listing and CRF list sequences that were disclosed in the application as filed. Accordingly, the amendment does not add impermissible new matter. The application now complies with the Sequence Rules, and the objection may be withdrawn.

8. Objection to the Claims

Claims 1 and 2 are objected for recited "SEQ. ID. No." The claims are amended to recite "SEQ ID NO," as suggested by the Office. The objection thus may be withdrawn.

9. Rejection under 35 U.S.C. § 101

Claims 1 and 2 are rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. The claims are amended to indicate that the protein and nucleic acid are "isolated," i.e., are products of the hand of man. The claims are directed to statutory subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Accordingly, the rejection should be withdrawn.

10. Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1-4 and 6-10 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly directed to subject matter requiring undue experimentation to make or use. Applicants traverse the rejection.

The Office acknowledges that the specification enables the subject matter of an isolated protein comprising the amino acid sequence of SEQ ID NO: 1, which has the activity of hydrolyzing dextran, starch, mutan, inulin, and levan. To expedite prosecution, claim 1 is

presumably by inadvertent reference to the IDSs filed in related Application Serial No. 10/588,052. Applicants seek clarification on this issue in the Office's next communication.

amended to recite what the Office acknowledges as enabled, and this aspect of the rejection accordingly should be withdrawn.

The Office further acknowledges that an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 2 is enabled. New claim 11 is directed to this subject matter.

Amended claim 2 recites an isolated polynucleotide encoding the protein of claim 1, i.e., the protein comprising the amino acid sequence of SEQ ID NO: 1. It was well known in the art at the time of the invention that multiple polynucleotide sequences can encode a particular amino acid sequence, given the known redundancy of the genetic code. *See, e.g., Wallace*, 71 U.S.P.Q.2d at 1942 (referring to *MOLECULAR BIOLOGY OF THE GENE*, Watson *et al.*, eds., Benjamin/Cummings, 3rd ed., pp. 356-57 (1977) for the proposition that the skilled artisan would know every combination of sequences of a polynucleotide that would encode a particular polypeptide). The artisan also knew how to construct polynucleotide sequences having any combination of nucleotide bases by routine synthetic chemistry, for example. *See, e.g., Sambrook et al. In MOLECULAR CLONING: A LABORATORY MANUAL*, 2nd ed., Cold Spring Harbor, N.Y., p. 8.49 (1989). Although a significant amount of experimentation would be required to make all polynucleotide sequences encompassed by the claim, the experimentation itself was routine and predictable, given this level of skill in the art. For these reasons, the experimentation would not be undue in nature. *See In re Wands*, 858 F.2d 731, 736, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (“the test [for undue experimentation] is not merely quantitative . . . if it is merely routine”). Because the experimentation required to make and use the claimed invention is not undue, claim 2 is enabled by the specification. Because the polynucleotide of claim 2 is enabled, the subject matter of the dependent claims 3-10 also is enabled. The rejection accordingly should be withdrawn.

10. Rejection under 35 U.S.C. § 112, First Paragraph (Biological Deposit)

Claim 5 is rejected as allegedly non-enabled, because the specification does not indicate whether the deposited microorganism will be available to the public. As shown in **Exhibit 1**, for

example, the deposited microorganism having Accession No. KCTC 10574BP was deposited under the terms of the Budapest Treaty. The undersigned attorney of record states that the deposited microorganism having Accession No. KCTC 10574BP will be released to the public irrevocably and without restriction or condition upon issuance of a patent. Applicants have satisfied the deposit requirements, and the rejection should be withdrawn.

11. Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1-4 and 6-10 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly inadequately described in the specification. Applicants traverse the rejection.

The protein of claim 1 is adequately described by the amino acid sequence of SEQ ID NO: 1, and the polynucleotide of claim 11 is adequately described by the nucleotide sequence of SEQ ID NO: 2. *See* Office Action, page 13. The polynucleotide of claim 2 is adequately described for the reasons set forth at Part 2, above. That is, the Office's reviewing court has held that the state of the art has developed such that a description of a complete amino acid sequence of a protein puts the artisan in possession of a genus of DNA sequences encoding it. *See Wallach*, 71 U.S.P.Q.2d at 1942. It follows that the description of the protein of SEQ ID NO: 1 puts the artisan in possession of a genus of nucleic acids encoding the protein of SEQ ID NO: 1. *See Id.* Because the polynucleotide of claim 2 is adequately described, the claims depending from claim 2 likewise are adequately described. The rejection accordingly should be withdrawn.

12. Rejections under 35 U.S.C. § 102

U.S. Patent No. 6,485,953 ("Kim")

Claims 1 and 7-10 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,485,953 ("Kim"). Applicants traverse the rejection.

To establish a *prima facie* case of anticipation, a single prior art reference must teach each and every element of the claimed invention, either explicitly or inherently. *Verdegaal Bros. v. Union Oil Co. Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Recognizing that the Office does not possess means to test inherent characteristics

experimentally, the Office's reviewing courts require the Office only to establish a reason to believe that a property is an inherent characteristic of the prior art. *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). The Office, however, must establish that the allegedly inherent characteristic *necessarily* inheres in the prior art teaching. *See, e.g., In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981) ("Inherency, however, may not be established by probabilities or possibilities.").

In the present case, the Office has not put forth adequate reasons or evidence that the protein disclosed in Kim is the same as the presently claimed protein. Like the claimed protein, the protein disclosed in Kim is a dextranase secreted from *L. starkeyi*. *L. starkeyi*, however, secretes a battery of dextranases and other glucanhydrolases. *See Kang et al.*, "Cloning and expression of *Lipomyces starkeyi* α -amylase in *Escherichia coli* and determination of some of its properties," *FEMS Microbiol. Lett.* 233: 53-64 (2004), page 62, right col. (citing references). The Office has established only a mere *possibility* that the Kim protein is indeed the protein of SEQ ID NO: 1 and not another of the battery of secreted proteins. This evidence is insufficient to make a case of inherent anticipation. *See Oelrich*, 666 F.2d at 581-82.

Further, there are differences in the properties of the protein of SEQ ID NO: 1 and the protein of Kim. For instance, [1] the apparent molecular weight is different between the two *L. starkeyi* enzymes. The protein of Kim exhibits an apparent molecular weight using 10% SDS-PAGE of 94 kDa and 60 kDa. Kim, col. 2, lines 41-46. The native protein of SEQ ID NO: 1 has an apparent molecular weight of about 68 kDa, and the expressed protein has an apparent molecular weight of 70 kDa. *E.g.*, Specification, page 17, lines 20-26.

[2] The temperature and pH optima for the enzymes are distinct. The protein of Kim shows an optimal pH for dextranase activity of pH 3.5-4.5 (Figure 1B). Most of the dextranase activity is lost at a pH of 5.5. By contrast, the protein of SEQ ID NO: 1 shows a broad pH dependence for dextranase activity (*see* Specification, page 13, line 18, *et seq.*). As shown in the specification at Figure 2, the presently disclosed protein retains nearly full activity at pH 7.7.

[3] The elution profile off of hydroxyapatite is different for the two enzymes. The dextranase of Kim elutes from hydroxyapatite in 50, 125, and 225 mM phosphate buffer solution. Kim, col. 7, lines 41-43. By contrast, the presently disclosed dextranase elutes off

hydroxyapatite in 300 mM phosphate buffer, meaning that it advantageously can bind teeth more strongly. *See, e.g.,* Specification, page 17, lines 13-18.

The Office alleges that it has put forth a reasonable case of inherency based simply on the fact that the presently disclosed protein and the protein of Kim are expressed in *L. starkeyi* and that their apparent molecular weights are somewhat similar. From the evidence set forth above, however, the protein of Kim is different from the protein of SEQ ID NO: 1. That is, the protein of Kim is a different enzyme of the battery of dextranases, amylases, and other glucanhydrolases secreted by *L. starkeyi*. The Office thus has not made a proper case of inherent anticipation. *See Oelrich*, 666 F.2d at 581-82. Accordingly, the rejection should be withdrawn.

U.S. Patent No. 5,637,491 ("Campana")

Claims 1-4 and 6-10 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,637,491 ("Campana"). Applicants traverse the rejection.

Campana discloses a protein sequence with about 78% sequence identity to SEQ ID NO: 1 and an encoding polynucleotide with 71% sequence identity to SEQ ID NO: 2. Office Action, pages 17-22. Campana discloses neither the protein having the sequence of SEQ ID NO: 1 nor the polynucleotide having the sequence of SEQ ID NO: 2. Further, the polynucleotide of Campana does not encode the protein of SEQ ID NO: 1. Campana thus does not teach all the elements of the claimed invention and does not anticipate the claims. The rejection accordingly should be withdrawn.

13. Rejections under 35 U.S.C. § 103

Claim 2

Claim 2 is rejected under 35 U.S.C. § 103 as allegedly obvious over Kim in view of Standing, *Curr. Opinion Struct. Biol.* 13(5): 595-601 (2003) ("Standing") and Sambrook *et al.* In MOLECULAR CLONING: A LABORATORY MANUAL, 2nd ed., Cold Spring Harbor, N.Y., pp 8.46-8.52 and 11.2-11.19 (1989) ("Sambrook"). Applicants traverse the rejection.

The Office at best makes a case that it would have been obvious for the artisan of ordinary skill to make a polynucleotide encoding the protein described in Kim. For the reasons

set forth in Part 12, above, the protein of Kim is not the same as the presently disclosed protein. It follows that the polynucleotide encoding the protein of Kim cannot be the same as the claimed polynucleotide encoding the protein of SEQ ID NO: 1 or the claimed polynucleotide of SEQ ID NO: 2. The Office has not made a case that it would have been obvious to make the claimed invention, and the rejection accordingly should be withdrawn.

Claims 3, 4, and 6

Claims 3, 4, and 6 are rejected under 35 U.S.C. § 103 as allegedly obvious over Kim in view of Standing and Sambrook with respect to claim 2 and further in view of U.S. Patent No. 5,643,758 ("Guan"). Applicants traverse the rejection.

Guan does not teach the claim elements not taught by the combination of Kim, Standing and Sambrook. Guan thus does not address the deficiencies of these references, alone or in combination. The proposed combination of references thus does render the claimed invention obvious. Accordingly, the rejection should be withdrawn.


CONCLUSION

In conclusion, this amendment and reply is believed to be a full response to the outstanding Office Action. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is respectfully requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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